



Safety Events and Privilege Utilization Rates in Advanced Practice Physical Therapy Compared to Traditional Primary Care: An Observational Study.

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1 Safety Events and Privilege Utilization Rates in Advanced Practice Physical Therapy 2 compared to Traditional Primary Care: An Observational Study

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4 Short Title: Advanced Practice Physical Therapy Safety & Utilization

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1 INTRODUCTION: The general practitioner shortage in the United States coupled with a
2 growing number of Americans living with disability has fueled speculation of non-
3 physician providers assuming a greater role in musculoskeletal healthcare. Previous
4 physician shortages have been similarly addressed, and expanding physical therapy
5 (PT) scope of practice may best serve to fill this need. Resistance to expanding PT
6 practice focuses on patient safety as PTs assume the roles traditionally performed by
7 primary care providers. While studies have shown advanced practice PT to be safe,
8 none have compared safety events in advanced practice PT compared to traditional
9 primary care to determine if there are increased patient risks. Therefore, the purpose of
10 our study is to examine the rate of safety events and utilization of services in an
11 advanced practice PT clinic compared to a primary care clinic. A secondary aim of our
12 study was to report safety events associated with spinal manipulation and dry needling
13 procedures.

14 MATERIALS & METHODS: Productivity and safety data were retrospectively collected
15 from Malcolm Grow Medical Center from 2015-2017 for the Family Health Clinic (FHC)
16 and an advanced practice Physical Therapy Clinic (PTC). Chi square tests for
17 independence, risk ratios (RR) and 95% confidence intervals (95%) were used to
18 compare the relationship between the frequency of 1) patient encounters and clinical
19 procedures and 2) clinical procedures and safety events.

20 RESULTS: 75% (12/16) of safety events reported in the PTC were defined as near
21 misses compared to 50% (28/56) within the FHC (RR 1.5; 95% CIs: 1.0 to 2.2). Safety
22 events were more likely to reach patients in the FHC compared to the PTC (RR 1.9;
23 95% CIs: 0.8 to 4.7). Safety events associated with minor harm to patients was n=4 and

n=3 in the FHC and PTC respectively. No sentinel events, intentional harm events, nor actual events with more than minor harm were reported in either clinic. Significant relationships indicated that prescriptions, laboratory studies, imaging studies and referrals, were all more likely to be ordered in the FHC than the PTC ($p<0.01$). The PTC ordered one diagnostic imaging study for every 37 encounters compared to one in every 5 encounters in the FHC. The PTC similarly referred one patient to another healthcare provider for every 52 encounters, fewer than the one per every 3 encounters in the FHC. There was a significant relationship between encounters and diagnoses, indicating a higher number of diagnoses per encounter in the FHC, though the difference of 0.31 diagnoses per encounter may not be clinically meaningful ($p<0.01$). A total of 1,818 thrust manipulations and 2,910 dry needling procedures were completed without any reported safety events.

CONCLUSION: These results suggest advanced practice PT has a similar safety profile to traditional primary care. The authority to order musculoskeletal imaging and refer to other clinicians were among the most commonly utilized privileges and may be of primary importance when establishing an advanced practice PT clinic. These results support research showing advanced practice PT may lead to reductions in specialty referrals, diagnostic imaging, and pharmaceutical interventions.

1 INTRODUCTION

2 The number of Americans living with a disability has increased by 26% in the last 2
3 decades.^{1,2} Musculoskeletal conditions are the second leading cause for disability in
4 the United States and are the leading reason for primary care visits.^{2,3} Despite the rise
5 in disability, the US has one of the lowest number of physician visits per capita.⁴
6 Potential reasons that Americans see their physicians so infrequently are limitations of
7 health care access and increasing costs. Health care costs in the US have grown
8 exponentially over the previous 2 decades.⁵ The Commonwealth Fund reported the
9 United States had the highest health care expenditure as a percentage of Gross
10 Domestic Product (GDP) and in health care spending per capita of the 18 industrialized
11 nations examined.⁴ One third of Americans reported cost-related barriers to
12 healthcare in the US, highest among examined countries.⁴ Only citizens of Switzerland
13 experience higher out of pocket health care costs than the US.⁴ In 2016, the
14 Organisation for Economic Co-Operation and Development (OECD) reported the US
15 has one of the lowest ratios of general practitioners per capita within reporting nations.⁶
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17 Previous US physician shortages have been addressed, in part, by expanding practice
18 of non-physician health care professions.^{7,8} Expanding the scope of care for US
19 physical therapists (PTs) may be a solution to help reduce health care costs while
20 improving access to care. In recent years, health care practices throughout the world
21 have been shifting away from more physician-centric models and transitioning to more
22 team-based approaches.⁹⁻¹¹ Further, research has found that team based approaches
23 benefit both patients as well as medical professionals.^{12,13} The shift to team-based care

has coincided with the physical therapy (PT) profession seeking and attaining greater levels of clinical responsibility.¹⁴ Specifically, all 50 states and the District of Columbia had some form of direct access by 2014.¹⁵ Additionally, Wisconsin became the first state to authorize radiograph orders by PTs in 2015.¹⁶ Despite this, there are still significant reimbursement and legislative hurdles to overcome in expanding PT scope of care. For instance, some state practice acts still restrict PTs from making a clinical diagnosis or from performing thrust manipulation.^{17,18}

PTs within the US military have been practicing in advanced roles since the 1970s.¹⁹ US military PTs operate as advanced practice PTs, and are authorized to see patients without a referral (direct access), and may order diagnostic imaging, laboratory studies, refer to other clinicians, and prescribe a limited set of medications. Additionally, all military PTs are authorized to perform thrust manipulations and may be credentialed to perform dry needling. This broad scope of practice has been called advanced practice PT, and is seldom realized in non-military settings within the US. Advanced practice PT has gained overwhelming support in the literature, both in the US and abroad. An abundance of research has shown that advanced practice PT has led to a decrease in health care utilization.²⁰⁻³¹ Patients treated by advanced practice PTs experience improved outcomes compared to traditional models.^{23-26,32,33} Perhaps most impactful is that advanced practice PT achieved these results while simultaneously reducing health care costs.^{20-22,24,25,27,29,32,34}

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4 46 Some of the main opponents of liberating restrictions on PT practice have argued such
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6 47 actions would put patients at increased risk of harm due to lower perceived educational
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9 48 standards when compared to primary care providers.^{35,36} Essentially, it is suggested
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11 49 PTs taking on responsibilities typically performed or ordered by primary care providers
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14 50 such as diagnosis, ordering musculoskeletal imaging, or ordering laboratory studies
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16 51 would receive inferior care compared to traditional primary care leading to a higher rate
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19 52 of adverse events. Subsequent evidence has shown PTs to have superior or similar
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21 53 knowledge of managing orthopedic conditions when compared to other medical
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24 54 professions.³⁷⁻⁴⁰ Further, all US PT programs advanced to an entry-level doctoral
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26 55 degree by 2017 which required the addition of pharmacologic, medical screening,
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29 56 nutrition, diagnostic imaging, and other content areas.^{41,42}
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33 58 Despite evidence supporting PT knowledge and education, safety of patients being
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36 59 treated by PTs in advanced roles remain a valid concern. While previous studies have
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39 60 shown advanced practice PT to be safe,⁴³⁻⁴⁵ it has not been shown how advanced
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41 61 practice PTs compare to primary care providers in relation to safety events. As
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43 62 advanced practice PTs take on responsibilities traditionally performed by primary care, it
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46 63 is unknown if patients are at a higher risk of an adverse event relative to the traditional
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49 64 primary care pathway. It is also unknown if advanced practice PT would result in lower
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51 65 utilization rates of ancillary services. Therefore, the purpose of our study is to examine
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53 66 the rate of safety events and utilization of services in an advanced practice physical
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56 67 therapy clinic compared to a primary care clinic. We hypothesized that advanced
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58 68 practice PTs would have similar rates of reported safety events and lower utilization
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when compared to primary care providers. A secondary aim of our study was to report safety events associated with treatment techniques which are not universally authorized within US PT practice acts (specifically: spinal manipulation and dry needling procedures).

METHODS

Data was retrospectively collected from Malcolm Grow Medical Clinic and Surgery Center (MGMC), Joint Base Andrews (JBA), Maryland from calendar years 2015-2017 for the Family Health Clinic (FHC) and Physical Therapy Clinic (PTC). MGMC is a United States Air Force (USAF) facility and primarily serves active duty military personnel, retired military personnel, and the dependents (including but not limited to spouses and children) of those personnel. At MGMC, patients with primary complaints which may potentially be musculoskeletal in nature (i.e. back pain, knee pain, etc) could contact the PTC directly to be seen as a direct access patient. Patients were also able to schedule appointments via centralized booking clerks, who were authorized to schedule patients either with the FHC or PTC depending on clinical availability. Patients scheduled with the FHC could be transferred to an on-site PT to be seen as direct access. Patients could also be referred to the PTC via a primary care provider, orthopedic surgeon, or other provider.(Figure 1)

The FHC utilizes medical doctors, doctors of osteopathy (DO), physician assistants, and nurse practitioners. The FHC is the main primary care clinic for patients largely within the ages of 18-64, as younger patients tend to be seen in Pediatrics and older or more-

sickly patients are typically seen within Internal Medicine. While DOs practiced as primary care providers in this setting, they could also perform joint manipulations in this setting.

The PTC is an advanced practice outpatient orthopedic clinic typically seeing patients aged 18-64 years. Within the JBA PTC, PTs may diagnose and treat patients with unlimited direct access, and may autonomously perform spinal manipulation or dry needling, order musculoskeletal imaging or laboratory studies, prescribe a limited set of medications, and refer to other healthcare providers such as orthopedic surgery. The PTC was staffed by physical therapists and physical therapy technicians. The PTs in this study included active duty military personnel, reserve military personnel, government civilians, and contractors.

PTs within USAF as a whole are mostly trained in civilian universities, with only 1-2 military trained PTs entering service per year. Similarly, most PTs within the JBA PTC during this period were trained through civilian PT programs, with only one PT graduating from U.S. Army-Baylor University. During the hospital credentialing process, PTs new to the military system are typically granted “supervised” privileges for advanced PT practice such as ordering diagnostic imaging. While under supervised privileges, the PT would need permission from a qualified PT to utilize an advanced practice skill and the supervising PT would subsequently cosign the corresponding clinical note. After successfully completing the 6 months of supervised privileges, the PT would typically advance to independent privileges. No additional formalized or

continuing education is mandated to attain advanced practice which speaks to the educational similarity of USAF PTs compared to a civilian practice.

Productivity statistics for all patient encounters and procedures for the FHC and PTC clinics for calendar years 2015-2017 were accessed via the Military Health System Management Analysis and Reporting Tool (M2). Procedures of interest included, 1) pharmaceutical prescriptions, 2) clinical diagnoses, 3) laboratory orders, 4) diagnostic imaging orders, 5) referrals to other clinics, 6) thrust manipulations, and 7) dry needling. In an effort to minimize risk, no identifiable patient data were accessed nor associated with the data set. The study was determined to be “non-human research” by the 59th Medical Wing Institutional Review Board (IRB) which is geographically separated from the clinics in this study but is nevertheless the governing IRB for said clinics.

Safety reports were pulled from the Patient Safety Reporting database (PSR). The PSR is an internal database which allows for documentation of safety events without fear of reprisal and not-accessible by legal entities. Reports may be entered by medical personnel within their clinic, medical personnel reporting a safety concern in another clinic, via patient complaints to the patient advocate, or via patient complaints to the safety officer. Patient Safety Reports are categorized into near miss, actual events, sentinel events, and intentional unsafe acts.⁴⁶ Near misses are considered to be potential unsafe event that never reaches a patient. Actual events are defined as events that have reached a patient and are subsequently categorized by the level of harm endured by the patient. Increasing near-miss reporting is thought to reduce actual

events.⁴⁷ The target benchmark of near-miss events for MGMC was at least 72% of overall safety reports. The command atmosphere during the collection period was one of non-retribution for completing safety reports. During the period of data collection, MGMC informed the researchers that the facility as a whole consistently surpassed the 72% near-miss metric suggesting safety reports were being documented at reasonable level. For the purposes of this study, PSR reports were further categorized by 2 blinded researchers using standard definitions (Table 1) consistent with PT practices that are not universally allowed within PT practice across the entire US. If there was disagreement on the categorization of a safety report, a third researcher served to break the tie.

Statistical analyses were performed in SPSS version 24.0 (IBM Corp), with $\alpha=0.05$ set a priori for all analyses. Chi square tests for independence, risk ratios (RR) and 95% confidence intervals (95%) were used to compare the relationship between the frequency of 1) patient encounters and clinical procedures and 2) clinical procedures and safety events in each of the previously mentioned categories. The procedure rate was calculated as the total procedures per 1000 encounters.

RESULTS

The number of providers practicing in the FHC per calendar year ranged from 15-21 physicians and 13-32 level-two providers (i.e. physician assistants or nurse practitioners). The number of providers practicing in the PTC per calendar year ranged from 6-11 PTs. Within the 3 years analyzed in this study, the FHC was responsible for

more encounters (207,241 vs. 41,656), prescriptions (208,946 vs. 28), diagnoses (357,549 vs. 59,234), laboratory studies (71,277 vs. 32), imaging studies (41,548 vs. 1,122), and referrals (67,652 vs 803) when compared to the PTC. There was a significant relationship between encounters and the following procedures in the FHC and PTC indicating that prescriptions ($\chi^2=38389.9$, $p<0.01$), laboratory studies ($\chi^2=13636.8$, $p<0.01$), imaging studies ($\chi^2=5790.1$, $p<0.01$) and referrals ($\chi^2=11221.0$, $p<0.01$), were all more likely to be used in the FHC than PTC. There was a significant relationship between encounters and diagnoses ($\chi^2=772.1$, $p<0.01$) in the FHC and PTC, indicating a higher number of diagnoses per encounter in the FHC than PTC, though a difference of 0.31 diagnoses per encounter may not be clinically meaningful.(Table 2)

There were 56 documented safety events within the FHC (of which 20 were categorized into 1 of the 7 procedural definitions and 36 which were categorized as “other”) and 16 within the PTC (all of which were categorized as “other”) (Table 3). The safety events in the “other” category were consistent with findings in previous studies⁴⁷ and included such items as failure in the electronic health records systems. 75% (12/16) of safety events reported in the PTC were defined as near misses compared to 50% (28/56) within the FHC (RR 1.5; 95% CIs: 1.0 to 2.2). Reciprocally, safety events were more likely to reach patients in the FHC compared to the PTC (RR 1.9; 95% CIs: 0.8 to 4.7). The number of safety events associated with minor harm to patients was n=4 and n=3 in the FHC and PTC respectively.(Table 4) No sentinel events, intentional harm events, nor actual events with more than minor harm were reported in either clinic.

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7 185 A total of 1,818 thrust manipulations (Figure 2) were performed with 197 and 1,621
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9 186 occurring in the FHC and PTC respectively. Within the PTC, 2,910 dry needling
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11 187 procedures were performed.(Figure 3) Within the three years of data collection, no
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14 188 safety report was filed in relation to a thrust manipulation nor a dry needling procedure.
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19 190 DISCUSSION

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21 191 Results indicate that PT has a similar safety profile to traditional primary care within the
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24 192 specified domains of advanced practice PT. This is consistent with previous studies
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26 193 which found no differences in harm-rates in advanced practice PT when compared to
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29 194 traditional referral-based PT.³⁴ This additionally supports research that shows PTs
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31 195 make correct triage decisions when presented with cases which may not be
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34 196 musculoskeletal in nature.⁴⁸⁻⁵⁰
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38 198 Mintken et al deemed advanced practice PT to be safe in their decade-long
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41 199 retrospective analysis. 12,976 patients were seen in PT at the University of Colorado
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43 200 without a physician referral. No serious medical pathology went unidentified, no
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46 201 adverse events were reported, and no licensure or disciplinary action of any kind was
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48 202 pursued against the PTs. Mintken et al concluded that patients were at “minimal to no
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51 203 risk for negligent care when evaluated and treated by PTs.” Moore et al reported a
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53 204 multicenter retrospective analysis reviewing advanced practice PT within 25 military
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56 205 clinics. During the 40 month analysis, 95 PTs recorded 472,013 encounters with no
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58 206 adverse events recorded, with no disciplinary action pursued, and with no litigation filed
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4 207 against the US Government.⁴³ Deyle concluded risks associated with advanced
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11 210 PTs were also found to utilize significantly fewer additional services such as laboratory
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13 211 studies and imaging when compared to FHC. These findings, however, are not
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15 212 intended to suggest superiority of either clinic in this regard as the roles of providers
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17 213 within the FHC and PTC are not identical. While advanced practice PTs utilize
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19 214 laboratory studies to screen for pathology, primary care providers must also use them
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21 215 for other functions such as tracking disease progression or identifying proper dosages
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23 216 for pharmaceutical interventions. Likewise, the number of images ordered by the PTC
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25 217 may be deflated if the patient had already received the imaging at the FHC. Rather, the
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27 218 reader should understand the utilization of services in expanded practice PT and use
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29 219 the FHC utilization only as a reference point.
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38 221 Notably, this study shows a PT imaging study order rate of 1 imaging study for every
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40 222 37.13 encounters or 2.69% of encounters. This is substantially lower than previous
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42 223 reports which have reported PT imaging rates of 10-15%.^{49,51} However, those studies
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44 224 reported imaging studies ordered “per patient” and not “per encounter” as in our study,
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46 225 which may explain these statistical differences. When looking at the domains of
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48 226 musculoskeletal imaging, laboratory studies, prescriptions, and referrals to other
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50 227 practitioners, the most commonly utilized skill of advanced practice PTs was to order
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52 228 diagnostic imaging studies. To that end, pursuing diagnostic imaging authority may be
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of utmost importance if pursuing advanced practice physical therapy within a practice act or within a healthcare organization.

The ability to refer to other clinicians such as orthopedic surgeons was a close second in order of utilization, occurring 1 in every 51.88 encounters or 1.93%. Similar to imaging orders, previous studies reported a substantially different rate of referral at 16%, but those studies were also reported “per patient” and not “per encounter” as we reported in this study.⁴⁹ Ordering laboratory studies and prescribing medicine were utilized markedly less frequently by the advanced practice PTs. Our findings are consistent with previous research into ancillary services utilization in direct access PT compared to traditional care.^{20,21,52,53} Frogner et al similarly found significant reductions in healthcare utilization including pharmaceuticals and imaging services when patients accessed physical therapy first before traditional care.²²

In recent years, dry needling has seen large gains in clinical application fueled by multiple legislative updates or legal decisions regarding its implementation by PTs. However, medical literature on dry needling is limited, especially as applied by PTs. This dearth of evidence is compounded when looking for risks associated with dry needling.⁵⁴ Brady et al performed a prospective study evaluating adverse events in 7,629 treatments of dry needling. Zero significant adverse events were reported, suggesting an upper significant risk rate of $\leq 0.04\%$.⁵⁵ Gonzalez-Perez et al performed a randomized controlled trial in which a total of 72 dry needling interventions were performed.⁵⁶ They reported no adverse events occurred within their treatment

population of 24 subjects. Cotchett et al treated 84 patients with weekly dry needling interventions for a period of six weeks in their randomized controlled trial, and no adverse events were reported.⁵⁷ In this study, 2,910 dry needling treatments were performed over a three-year period by PTs with zero reported safety events. Our findings are consistent with multiple literature reviews which have reported no significant adverse events or a low level of risk from dry needling.⁵⁸⁻⁶⁰

Reporting of adverse events (or lack thereof) in spinal manipulation trials has significantly improved since 2010 when the Consolidated Standards of Reporting Trials statement was published.⁶¹ The subsequent literature has consistently reported adverse events tied to thrust manipulations to be absent or minor and transient.⁶²⁻⁷⁰ Studies which have reported adverse events in relation to manipulative therapy have been determined to be anecdotal without a clear connection between the treatment and the adverse event.^{71,72} Multiple systematic reviews have concluded thrust manipulation is low-risk⁷³⁻⁷⁶ Despite the reported safety of thrust manipulation as well as physical therapist application of the techniques, there are still practice acts within the US which limit PTs from practicing these techniques.

One of the criticisms of safety reporting within the contexts of spinal manipulation is “competing intra- and inter-professional narratives” which can influence reporting and study results.⁷⁷ To that end, Rozmovits et al suggested a collaborative and anonymous inter-professional reporting system which would liberate reporting from associated consequences, promoting greater learning opportunities.⁷⁷ To some extent, this study

touches on those aims as the PSR is an anonymous inter-professional reporting system. It is notable that a combined 1,817 thrust manipulations (197 FHC, 1,621 PTC) were performed with no reported safety events. However, a larger database of interventions must be assessed given serious events tied to spinal manipulation are rare and are estimated to occur once in every 20,000 to 250,000,000 manipulations.⁷⁸

Limitations of this study include being a single-center study in a military beneficiary population, which limits the generalizability of our results. Additionally, the PSR system is not inherently sensitive, as more significant safety and/or harm events would likely be captured within this system while more mild adverse events such as post manipulation soreness or mild medication side effects would not likely be captured. Mild, transient, and self-limiting adverse events, however, would similarly not be likely to drive legislative decisions which we've approached in this paper. While limiting patient data allowed for a much wider collection of encounter data, it limited our ability to more closely match or compare patient populations between the FHC and PTC. The magnitude of the data collection spanning approximately 249,000 encounters also restricted the ability to collect outcomes, though previous research has consistently found superior outcomes within advanced practice PT.^{23-26,33} While the literature is supportive of advanced practice PT, research on adverse events within this practice setting are limited. Further research on safety rates within advanced practice PT settings will be useful to support PT practice act expansions.

CONCLUSION

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298 Advanced practice PT has a similar safety profile and lower utilization rates of ancillary
299 services when compared to traditional primary care within their respective patient
300 populations. This may indicate that advanced practice PT can provide a safe and
301 efficient first line of treatment for MSK conditions.

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FIGURES

Figure 1. Patient flow diagram

Figure 2. Number of spinal manipulation procedures per month in the Physical Therapy Clinic (PTC) and the Family Health Clinic (FHC)

Figure 3. Number of dry needling procedures per month in the Physical Therapy Clinic

Figure 1

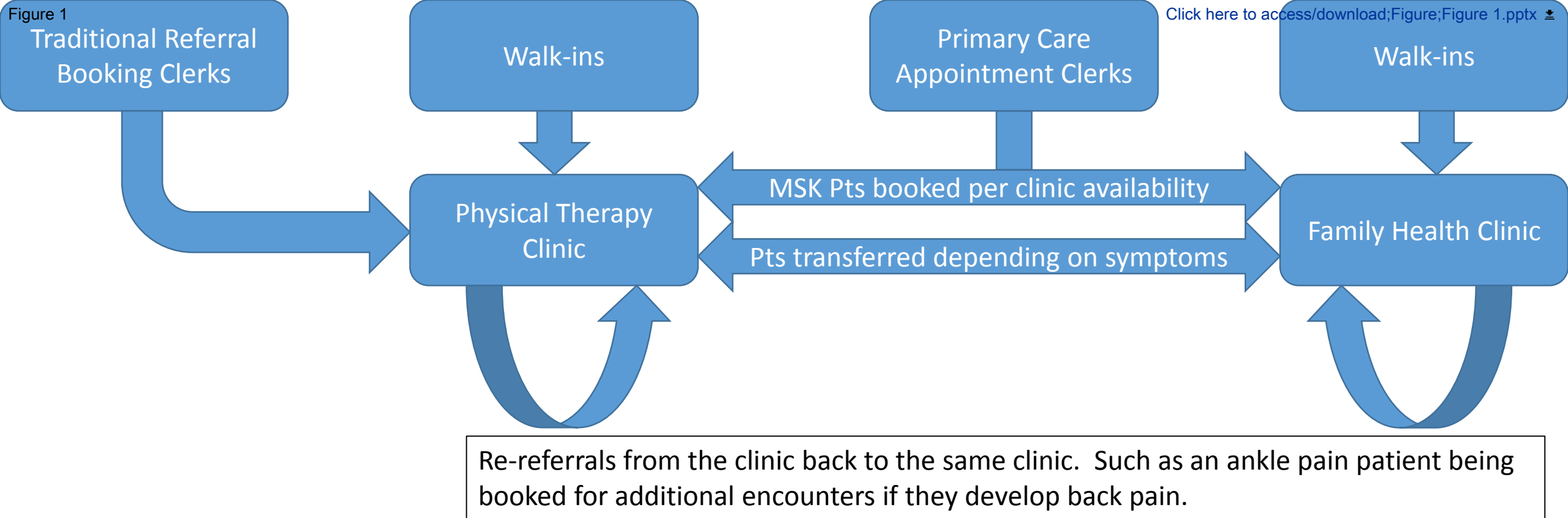


Figure 2

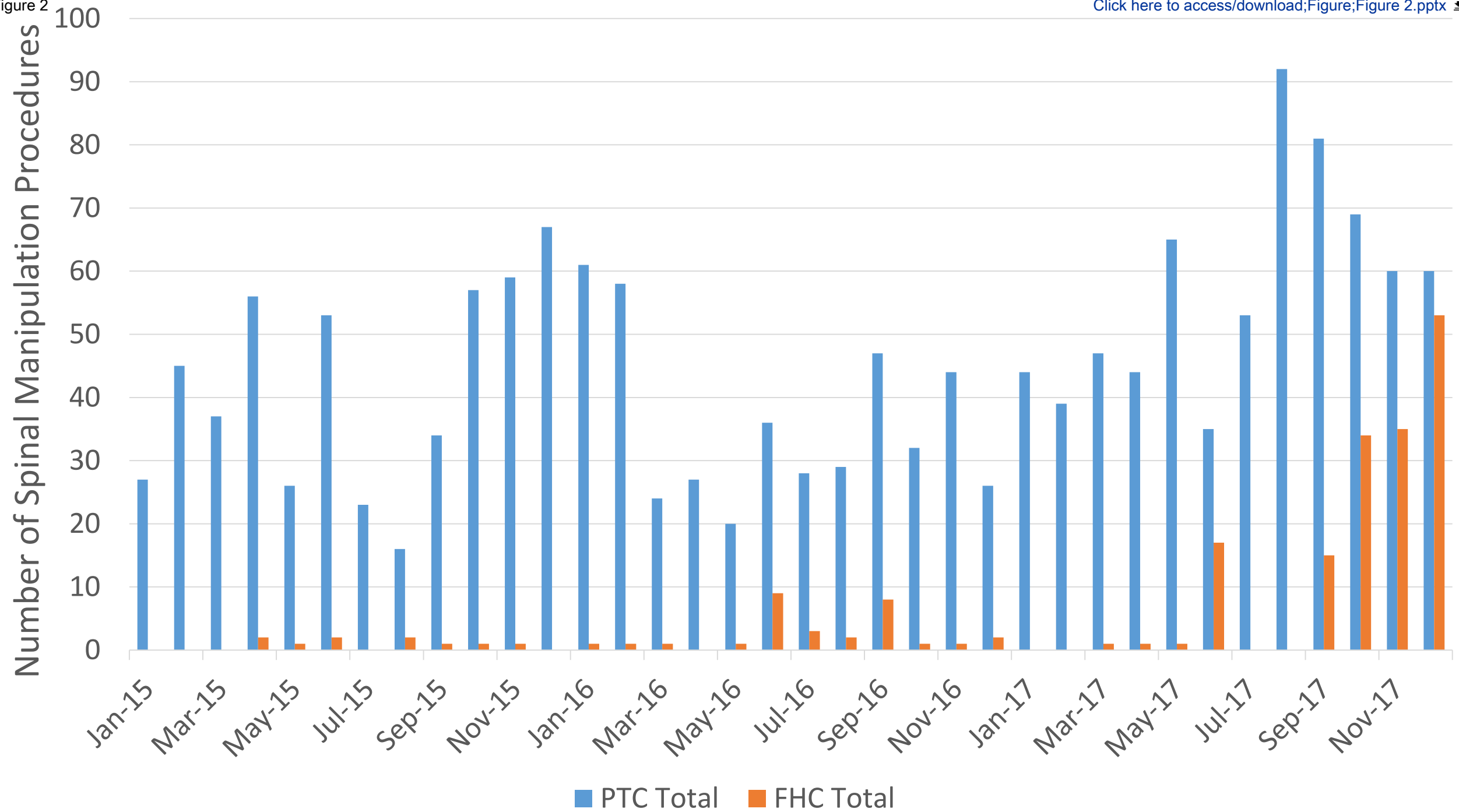


Figure 3

Number of Dry Needling Procedures

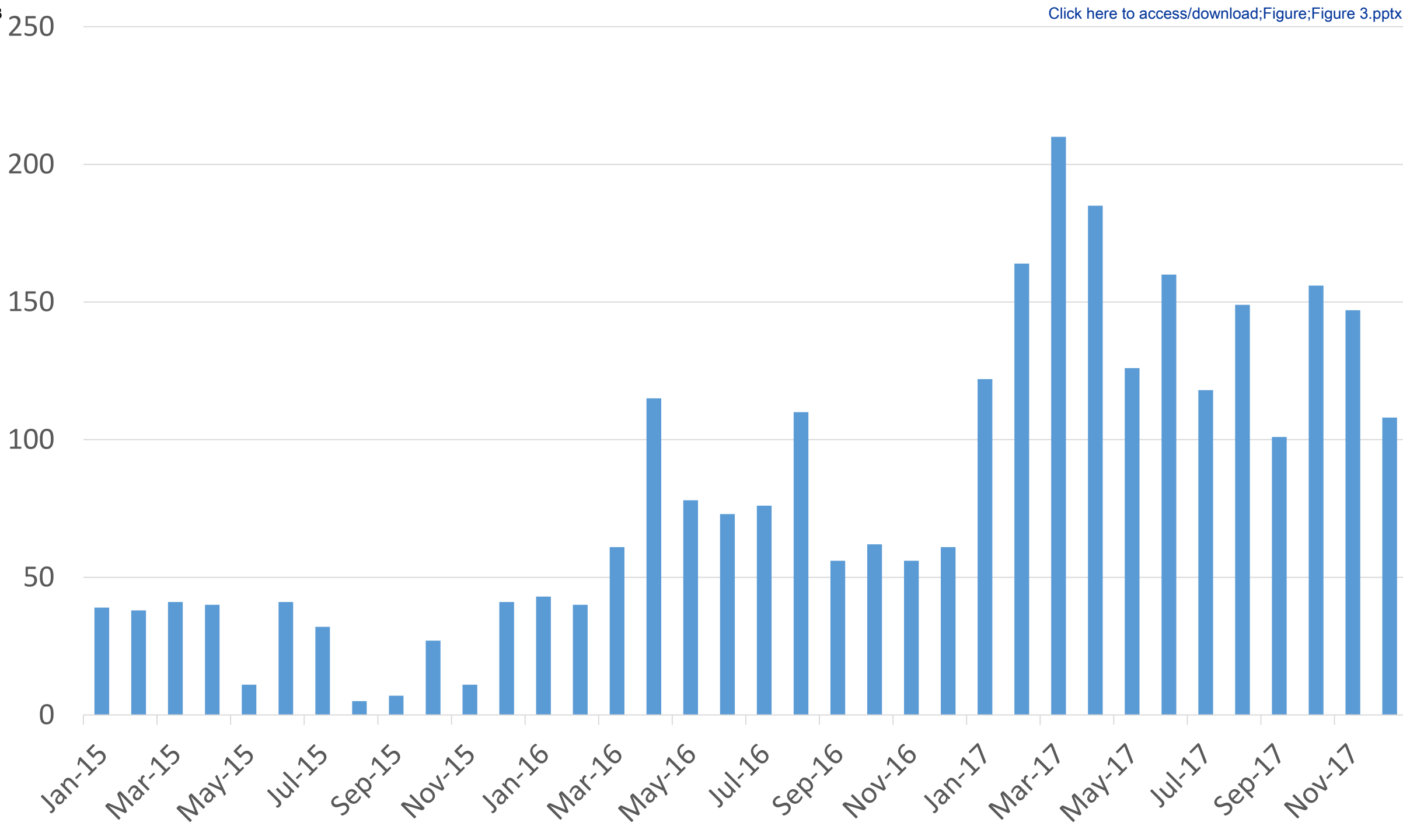


Table 1. Safety Event Category Definitions

Category	Definition
Prescription	Safety event stemming from an improperly ordered prescription, a contraindicated prescription, or other harm caused by a prescription which was faulted to the provider/clinic
Diagnosis	Safety event stemming from a missed diagnosis, a failure to report diagnosis to patient, or any other diagnosis related event which was faulted to the provider/clinic
Laboratory Study	Safety event stemming from an improperly ordered laboratory study, a failure to order a laboratory study, or a failure to report to patient the outcome. In an effort to homogenize data, safety events occurring during the collection or handling of laboratory studies were not included as the Physical Therapy Clinic does not perform laboratory collection.
Diagnostic Imaging	Safety event stemming from an improper order for a diagnostic image, a failure to order an appropriate diagnostic image, or other diagnostic imaging events which was faulted to the provider/clinic.
Referral (Out)	Safety event stemming from an improper referral, referral to the wrong clinic, failure to inform patient of a referral, or any other referral related event which was faulted to the provider/clinic
Thrust Manipulation	Safety event stemming a thrust manipulation potentially from improper application, contraindication, or other thrust manipulation event which was faulted to the provider/clinic
Dry Needling	Safety event stemming from dry needling potentially from improper application, contraindication, or other dry needling event which was faulted to the provider/clinic
Other	Any safety event not otherwise captured by any other category

Table 2. Advanced Practice Utilization

	FHC	PTC	p-value
Encounters (Enc)	207,241	41,656	
Prescriptions (Rx)	208,946	28	**<0.01
Enc/Rx	0.99	1,487.71	
Diagnoses (Dx)	357,549	59,234	**<0.01
Dx/Enc	1.73	1.42	
Laboratory Studies (Lab)	71,277	32	**<0.01
Enc/Lab	2.91	1,301.75	
Imaging Studies (IS)	41,548	1,122	**<0.01
Enc/IS	4.99	37.13	
Referrals (Ref)	67,652	803	**<0.01
Enc/Ref	3.06	51.88	

FHC - Family Health Clinic; PTC - Physical Therapy Clinic

** Indicates a statistically significant finding

Table 3. Safety Event Analysis

	FHC	PTC	p-value
Encounters (Enc)	207,241	41,656	
Total Safety Reports	56	16	0.21
Total Safety Reports/100,000 Encs	27.02	38.41	
Prescriptions (Rx)	208,946	28	
Rx Safety Reports	11	0	0.97
Rx Safety Reports/100,000 Rxs	5.26	0.00	
Diagnoses (Dx)	357,549	59,234	
Dx Safety Reports	4	0	0.42
Dx Safety Reports/100,000 Dxs	1.12	0.00	
Laboratory Studies (Lab)	71,277	32	
Lab Safety Reports	3	0	0.97
Lab Safety Reports/100,000 Labs	4.21	0.00	
Imaging Studies (IS)	41,548	1,122	
IS Safety Reports	1	0	0.87
IS Safety Reports/100,000 IS	2.41	0.00	
Referrals (Ref)	67,652	803	
Ref Safety Reports	1	0	0.91
Ref Safety Reports/100,000 Ref	1.48	0.00	

FHC - Family Health Clinic; PTC - Physical Therapy Clinic

Table 4. Safety Event Harm Level

	Family Health					
Category	Safety Reports	Near Miss	Near Miss %	Actual Event	No Harm	Mild Harm
Other	36	23	64%	13	12	1
Medication	11	1	9%	10	8	2
Diagnosis	4	0	0%	4	3	1
Laboratory	3	3	100%	0	0	0
Imaging	1	1	100%	0	0	0
Referral	1	0	0%	1	1	0
Thrust Manipulation	0	0	N/A	0	0	0
Dry Needling	N/A	N/A	N/A	N/A	N/A	N/A
Total	56	28	50%	28	24	4

	Physical Therapy					
Category	Safety Reports	Near Miss	Near Miss %	Actual Event	No Harm	Mild Harm
Other	16	12	75%	4	1	3
Medication	0	0	N/A	0	0	0
Diagnosis	0	0	N/A	0	0	0
Laboratory	0	0	N/A	0	0	0
Imaging	0	0	N/A	0	0	0
Referral	0	0	N/A	0	0	0
Thrust Manipulation	0	0	N/A	0	0	0
Dry Needling	0	0	N/A	0	0	0
Total	16	12	75%	4	1	3

59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59th Clinical Research Division/SGVUS/(210) 292-7143
1100 Wilford Hall Loop, Bldg 4430, Lackland AFB, TX 78236-5300

10 Jan 18

FINAL DETERMINATION –NON-HUMAN RESEARCH

Determination Date: 10 Jan 2018

Project Lead: Maj Lance Mabry/11SGC

Reference Number: FWH20180057N

Project Title: Reported Harm in Military Physical Therapists Practicing in Expanded Roles: A Single Center Study

You may begin your project, as you would any other clinical or operational activity, with the approval and sponsorship of your leadership.

Your project was determined on 10 Jan 2018 to be considered **not human research** as defined by DoD regulation **32 CFR 219 and FDA regulation 21 CFR 56**. Continued IRB oversight for this activity is not required. The proposed project does not include non-routine intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction, nor do the researchers obtain private, identifiable information about living individuals.

Since the IRB does not have regulatory oversight for your study, it is the investigator's responsibility to validate the study's scientific merit and research design and to ensure the conduct of the study is upheld by the highest ethical standards, as required by the Wing. Should you require assistance in reviewing the scientific merit and research design of your study, please contact the Protocol Office. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander.

In accord with DoDI 6000.08 any intramural funding of this study as research or as a clinical investigation may continue to be received or sought regardless of this IRB determination.

Your study has received a one-time research determination. If the goals and/or activities of the project change during the course of the project, or if new activities are proposed that would constitute human subjects research, re-contact the Protocol Office, so that a regulatory expert may determine whether or not the revised plan involves human subject research activities.

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Earl Grant, Jr., PhD
Designated Exempt Reviewer